

# **NUCLEAR REGULATORY COMMISSION**

## **10 CFR Part 63**

**[Docket No. PRM-63-1]**

### **State of Nevada; Denial of a Petition for Rulemaking**

**AGENCY:** Nuclear Regulatory Commission

**ACTION:** Petition for Rulemaking: Denial

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking submitted by the State of Nevada. The petitioner requests that the NRC amend its regulations governing the disposal of high-level radioactive wastes in a proposed geologic repository at Yucca Mountain, Nevada. The petitioner believes that the present regulations are deficient because, in petitioner's view, they do not provide the regulatory framework to ensure that the repository isolates high-level radioactive waste over the long term primarily by geologic means and they do not demand that the applicant provide an "affirmative safety case" for the repository. These deficiencies, in petitioner's view, indicate that the regulations are not in full compliance with the Nuclear Waste Policy Act of 1982, as amended (NWPA), and/or the Atomic Energy Act of 1954, as amended (AEA). The NRC is denying the petition because: petitioner's assertion that Part 63 is not in full compliance with NWPA or AEA is completely without substance; and the petition does not appear to present significant new factual information or policy recommendations

that the Commission did not consider in the recent rulemaking which established Part 63 and it would be an unwise expenditure of resources to reconsider issues resolved in that rulemaking.

**ADDRESSES:** Copies of the petition for rulemaking and the NRC's letter to the petitioner are available on NRC's rulemaking Web site at <http://ruleforum.llnl.gov>. For information about the interactive rulemaking Web site, contact Carol Gallagher (301) 415-5905 or Toll Free: 1-800-368-5642; e-mail: [cag@nrc.gov](mailto:cag@nrc.gov). The documents may also be examined at the NRC Public Document Room (PDR), Room O-1F23, 11555 Rockville Pike, Rockville, MD.

The NRC maintains an Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. These documents may be accessed through NRC's Public Electronic Reading Room on the Internet at <http://www.nrc.gov/reading-rm/adams.html>. If you do not have access to ADAMS, or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1-800-397-4209, or 301-415-4737; or by e-mail to: [pdr@nrc.gov](mailto:pdr@nrc.gov).

**FOR FURTHER INFORMATION CONTACT:** Timothy McCartin, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-7285 or Toll Free: 1-800-368-5642, e-mail: [tjm3@nrc.gov](mailto:tjm3@nrc.gov); or Clark Prichard, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6203 or Toll Free: 1-800-368-5642, e-mail: [cwp@nrc.gov](mailto:cwp@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

**The Petition**

On July 12, 2002, the State of Nevada submitted a "Petition to Institute Rulemaking: Part 63" (Petition) which was docketed as a petition for rulemaking under 10 CFR 2.802 of the Commission's regulations (PRM-63-1). The petition requests amendments to 10 CFR Part 63, NRC's regulations governing the disposal of high-level radioactive waste (HLW) in a proposed geologic repository at Yucca Mountain, Nevada (YM). Petitioner believes that its proposed amendments are needed to bring Part 63 into full compliance with the Nuclear Waste Policy Act of 1982, as amended, 42 U.S.C. sec. 10101 et seq. (NWPA), and to ensure that the Part 63 regulations, if met by the Department of Energy (DOE or Applicant), will provide reasonable assurance of the safety of the repository. Petition at 3.

Specifically, the petition requests the following amendments to Part 63:

1. Section 63.15 Site Characterization.

At present, § 63.15(a) provides:

(a) DOE shall conduct a program of site characterization with respect to the Yucca Mountain site before it submits an application for a license to be issued under this part.

Petitioner requests that the following two sentences be added:

DOE's site characterization shall include criteria, developed pursuant to section 112(a) of the NWPA, to be used to determine the suitability of the Yucca Mountain site for the location of a geologic repository. Such criteria shall ensure that the geologic setting of the Yucca Mountain site is the primary barrier against the release of radionuclides to the biosphere from the multi-barrier repository system.

Petition at 40.

## 2. Section 63.21 Content of application.

Petitioner requests that the first sentence of paragraph (a) be modified, and new paragraphs (c) and (d) be added, as follows:

(a) An application consists of general information, a Safety Analysis Report, documentation propounding an affirmative safety case for the Yucca Mountain repository, and documentation that the site does not have any material disqualifying conditions. \* \* \*

\* \* \*

(c) The affirmative safety case must include:

(1) A realistic assessment of system evolution and radionuclide migration, drawing on natural and historical analogs.

(2) Documentation evidencing an overall understanding by the applicant of the key safety-relevant factors in the repository system, communicated in a manner that aids in public understanding.

(3) Disaggregated dose projections with documentation of which particular factors or sub-scenarios can lead to large potential doses, explaining as well the likelihood of occurrence of such scenarios.

(4) Use of multiple performance measures showing, at a minimum, the effects of each isolation barrier and the spatial and temporal distribution of radionuclides within each component of the repository system.

(5) A simplified interpretative or insight model containing only the key processes affecting safety, for use by the Commission and the public to assess the safety of the repository.

(6) Documentation of the major conservatisms and optimisms in the total system performance analysis, and quantification of their impacts with respect to realistic post-closure assumptions.

(7) Documentation of extreme conditions which might give rise to doses above prescribed regulatory criteria, and a description of the factors that make these situations unlikely.

(8) A description and prioritization of the isolation features that are considered important to keep releases and doses within regulatory limits and as low as is reasonably achievable.

(9) Documentation of where the major uncertainties lie in the total system performance assessment and how the applicant will mitigate such uncertainties.

(10) Documentation of a sensitivity case where engineered barriers are rendered ineffective, individually and collectively.

(11) Presentation of the key features and results for each material subscenario in the repository system.

(12) A comparison of and rebuttal to results of any scientific peer review of the applicant's total system performance assessment and/or its underlying science performed by the Nuclear Waste Technical Review Board, the International Atomic Energy Agency, or other peer reviewer designated by the applicant or the Commission.

(d) Potentially disqualifying conditions. The following conditions are to be considered adverse and potentially disqualifying if they are characteristic of the post-closure controlled area at Yucca Mountain or may materially affect isolation within the controlled area. The application shall demonstrate that these disqualifying conditions do not exist or, if they do exist, that they are not materially adverse to the long-term safety of the repository.

(1) Potential for flooding of the underground facility.

(2) Potential for natural phenomena such as subsidence or volcanic activity of such a magnitude that large-scale surface water impoundments could be created that could change the regional groundwater flow system and thereby adversely affect the performance of the repository.

(3) Structural deformation, such as uplift, subsidence, folding, or faulting that may adversely affect the regional groundwater flow system.

(4) Potential for changes in hydrogeologic conditions that would affect the migration of radionuclides to the accessible environment, such as changes in hydraulic gradient, average interstitial velocity, storage coefficient, hydraulic conductivity, natural recharge, potentiometric levels, and discharge points.

(5) Potential for changes in hydrologic conditions resulting from reasonably foreseeable climatic changes.

(6) Groundwater conditions in the host rock, including chemical composition, high ionic strength or ranges of Eh-pH, that could increase the solubility or chemical reactivity of the engineered barrier system.

(7) Geochemical processes that would reduce sorption of radionuclides, result in degradation of the rock strength, or adversely affect the performance of the engineered barrier system.

(8) Groundwater conditions in the host rock that are not reducing.

(9) Evidence of dissolution such as breccia pipes, dissolution cavities, or brine pockets.

(10) Structural deformation such as uplift, subsidence, folding, and faulting during the Quaternary Period.

(11) Earthquakes that have occurred historically that if they were to be repeated could affect the site significantly.

(12) Indications, based on correlations of earthquakes with tectonic processes and features, that either the frequency of occurrence or magnitude of earthquakes may increase.

(13) More frequent occurrence of earthquakes or earthquakes of higher magnitude than is typical of the area in which the geologic setting is located.

(14) Evidence of igneous activity since the start of the Quaternary Period.

(15) Evidence of extreme erosion during the Quaternary Period.

(16) The presence of naturally occurring materials, whether identified or undiscovered, within the site, in such form that:

(i) Economic extraction is currently feasible or potentially feasible during the foreseeable future; or

(ii) Such materials have greater gross value or net value than the average for other areas or similar size that are representative of and located within the geologic setting.

(17) Rock or groundwater conditions that would require complex engineering measures in the design and construction of the underground facility or in the sealing of boreholes and shafts.

(18) Geomechanical properties that do not permit design of underground opening that will remain stable through permanent closure.

(19) Potential for the water table to rise sufficiently so as to cause saturation of an underground facility located in the unsaturated zone.

(20) Potential for existing or future perched water bodies that may saturate portions of the underground facility or provide a faster flow path from an underground facility located in the unsaturated zone to the accessible environment.

(21) Potential for the movement of radionuclides in a gaseous state through air-filled pore spaces of an unsaturated geologic medium to the accessible environment.

Petition at 40 - 43

### 3. Section 63.113 Performance objectives for the geologic repository after permanent closure.

Petitioner requests that new paragraphs (e) and (f) be added to this section, as follows:

(e) *Geologic Setting*. The geologic setting for the Yucca Mountain repository shall evidence a pre-waste-emplacement groundwater travel time along the fastest path of likely radionuclide travel from the disturbed zone to the accessible environment of at least 1,000 years.

(f) *Peak Dose*. The geologic setting for the Yucca Mountain repository shall evidence sufficient geologic suitability to provide reasonable assurance that peak radiation doses to the accessible environment will not occur subsequent to the regulatory monitoring period established by the Environmental Protection Agency in 40 CFR Part 197.

Petition at 43.

### 4. Section 63.115 Requirements for multiple barriers.

Petitioner requests that a new paragraph (d) be added to this section, as follows:

(d) The natural features of the geologic setting shall constitute the primary barrier for assuring the long-term isolation of high-level radioactive waste and spent nuclear fuel at the proposed geologic repository at Yucca Mountain.

Petition at 44.

5. Section 63.311 Individual protection standard after permanent closure.

Petitioner requests that the words "a reasonable expectation" in this section be replaced with the words "reasonable assurance" so that it reads as follows:

DOE must demonstrate, using performance assessment, that there is reasonable assurance that, for 10,000 years following disposal, the reasonably maximally exposed individual receives no more than an annual dose of 0.15 mSv (15 mrem) from releases from the undisturbed Yucca Mountain disposal system. DOE's analysis must include all potential pathways of radionuclide transport and exposure.

In addition, petitioner requests that § 63.304, providing a definition of "reasonable expectation," be deleted in its entirety.

**Supporting Information**

Petitioner believes that the present Part 63 rule is "materially deficient" for two reasons: (1) it "does not now provide the regulatory framework to assure that the repository isolates [HLW] over the long term primarily by geologic means;" and (2) it "does not demand of the applicant that it provide an affirmative safety case for the repository." Petition at 4. Lacking these two "fundamental prerequisites," Part 63, in petitioner's view, "fails to assure the long-term safety of the repository or its compliance with the statutory requirements of the NWPA." Id. Petitioner's proposed amendments, taken as a whole, are designed to cure these alleged deficiencies.

The primacy of geologic criteria for HLW isolation.

Petitioner asserts that 10 CFR Part 63 must be revised such that it assures that the repository will isolate HLW primarily by geologic means both as a matter of law and as a matter of sound science. To support its "law" position, petitioner argues that the plain language of sections 112(a) and 113(b)(1) of NWPA, together with the legislative history of these sections, requires that geologic isolation be the primary form of containment for waste at the YM repository. Petition at 11 - 18. In particular, petitioner believes that the mandate in section 112(a) to DOE to issue guidelines for the recommendation of sites for repositories which, inter alia, must "specify detailed geologic considerations that shall be primary criteria for the selection of sites in various geologic media" and which "shall specify factors that qualify or disqualify any site from development as a repository, including factors pertaining to ... hydrology, geophysics [and] seismic activity...." means that NRC must set the same requirements for the YM repository. Petition at 11 - 12.

To support its "sound science" position, petitioner provides a detailed history of scientific studies that petitioner says underlie "the requirement of Section 112(a) of the NWPA that any



repository in this nation must isolate radioactive waste primarily by geologic means.” Petition at 6; see Petition at 6 - 11. Petitioner also points to the Affidavit of Dr. John W. Bartlett, a former Director of DOE’s HLW program at YM. Petition, Attachment 1. Dr. Bartlett questions DOE’s finding that YM is a site suitable for a repository. He does not comment on NRC’s regulations except to observe the different functions of the two agencies in Congress’ scheme for a repository: “Congress made it clear that DOE was to determine the suitability of the site, while the NRC was to determine the licenseability of the repository system (i.e., the site plus its engineered features).” Id. at 9 (emphasis in original).

Petitioner states that, initially, NRC, DOE and EPA each published rules which “individually and collectively conformed generally to the requirements of NWSA Section 112,” i.e., 10 CFR Part 60, 10 CFR Part 960 and 40 CFR Part 191, respectively. Petition at 18. Petitioner notes that, with respect to Part 60, the Commission decided to set subsystem performance requirements that serve the function of qualifying and disqualifying criteria for site variables, such as groundwater travel time, radionuclide travel times and margin of safety (assuming failure of the engineered barriers) but that the Commission “abandoned” these requirements in Part 63. Petition at 21- 22. Petitioner believes that this abandonment not only violates NWSA but also violates “NRC’s legal obligation [under section 161b. of the Atomic Energy Act] to apply these basic scientific prerequisites in providing for reasonable assurance of the safety of the repository....” Id.

The need for an affirmative safety case.

Petitioner also contends that 10 CFR Part 63 must be revised so that it requires DOE, as the applicant for a license, to present "an affirmative safety case" for the repository. Petitioner admits that "[a]s written, Part 63 arguably provides the regulatory framework to establish whether the Yucca Mountain repository will satisfy the radiological release criteria set by [EPA]," Petition at 4, but believes that this is insufficient to demonstrate that the repository is safe. According to petitioner, to demonstrate that the repository is safe, NRC must require demonstration of an understanding of repository performance, including that the geologic setting of the repository will, in fact, protect the public from the danger of radioactive releases whenever such releases might occur. Petition at 33 - 34. At present, petitioner asserts, the repository will become most dangerous to humans and the environment after the 10,000 year regulatory time period, a "blatantly unsafe condition" which should prevent the licensing of the repository. Petition at 33; see Attachment 2. Petitioner supports its view that an affirmative safety case is needed by incorporating criticisms of DOE's Total System Performance Assessment for the site recommendation process (TSPA-SR) made in a report by an international peer review, An International Peer Review of the Yucca Mountain Project TSPA-SR, March 2002 (Peer Review).<sup>1</sup> Petition at 34 - 38. Petitioner also cites criticisms of DOE's scientific work in preparation for a site recommendation made by the Nuclear Waste Technical Review Board and NRC's Advisory Committee on Nuclear Waste. Petition, Attachment 3.

### **Reasons for Denial**

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<sup>1</sup>DOE issued its TSPA-SR in December 2000. DOE subsequently requested a peer review which was carried out by a review team selected by the Nuclear Energy Agency of the Organization for Economic Co-Operation and Development and the International Atomic Energy Agency.

NRC is denying the petition because:

(1) Petitioner's assertion that 10 CFR Part 63 is not in full compliance with NWPA or AEA is without substance.

(2) The Commission promulgated 10 CFR Part 63 little over a year ago after an extensive rulemaking process that provided an enhanced level of stakeholder participation. The petition does not appear to present any significant new factual information or policy recommendations that the Commission has not already considered and it would be an unwise expenditure of resources to reconsider issues so recently resolved in the Part 63 rulemaking.

1. 10 CFR Part 63 is in full compliance with statutory requirements.

Petitioner asserts that current Part 63 regulations are not in full compliance with NWPA. Petition at 3. This is because, in petitioner's view, the current rule does not "provide the regulatory framework to assure that the repository isolates high-level radioactive waste over the long term primarily by geologic means." Petition at 4. Petitioner further asserts that the rule is deficient, under section 161b. of the Atomic Energy Act of 1954, as amended (AEA), 42 U.S.C. sec. 2201(b), because the rule does not require the applicant to provide "an affirmative safety case" for the repository. Petition at 4, 22. Petitioner misreads the Commission's duty under both of these statutes. As explained below, the Commission finds no legal infirmity in the current Part 63 regulations and thus there is no reason to amend Part 63 to cure any supposed lack of conformity with NWPA or AEA.

a. 10 CFR Part 63 is in accord with NWPA requirements.

Congress first spelled out directions for rulemakings to be undertaken to set requirements for a repository in section 121 of NWPA as enacted in 1982, 42 U.S.C. sec. 10141. The Environmental Protection Agency (EPA) was to “promulgate generally applicable standards for protection of the general environment from offsite releases from radioactive material in repositories” (sec. 121(a)), and NRC, “pursuant to authority under other provisions of law,” was “by rule, [to] promulgate technical requirements and criteria that it will apply ... in approving or disapproving ... applications for authorization to construct repositories [and] applications for licenses to receive and possess spent nuclear fuel and [HLW] in such repositories ....” (sec. 121(b)(1)(A)). Congress placed only three restrictions on the substance of the regulations NRC was to promulgate:

(1) NRC’s criteria “shall provide for the use of a system of multiple barriers in the design of the repository “ (sec. 121(b)(1)(B));

(2) NRC’s criteria “shall include such restrictions on the retrievability of the solidified [HLW] and spent fuel emplaced in the repository as the Commission deems appropriate” (sec. 121(b)(1)(B)); and

(3) NRC’s criteria “shall not be inconsistent with any comparable standards promulgated by the Administrator under subsection (a)” (sec. 121(b)(1)(C)).

The first of these restrictions shows that although Congress did require NRC to provide for “multiple barriers” for waste isolation, it did not specify that geologic barriers must be primary or qualify the “multiple barriers” requirement in any other way.

Congress amended NWPA in 1987 to focus the national waste program exclusively on the characterization of the YM site as a potential geologic repository but did not alter section 121 or otherwise place a requirement on NRC to make geologic barriers the primary means of waste isolation in its rules. Pub. L. 100-203 (101 Stat. 1330). Congress again revised the national waste program in the Energy Policy Act of 1992 (EnPA), Pub. L. 102-486, October 24, 1992. In the EnPA, Congress directed EPA to promulgate standards applicable solely to the Yucca Mountain site and directed NRC to modify its technical requirements and criteria under section 121(b) of NWPA, as necessary, to be consistent with EPA's standards. Section 801 of EnPA. EnPA did not direct either EPA or NRC to require that geologic barriers be the primary form of waste isolation.<sup>2</sup>

NRC initially established its procedural rules for a repository in 1981 in a new 10 CFR Part 60. (46 FR 13971; February 25, 1981). In 1983, NRC incorporated technical requirements into Part 60, as directed by NWPA. (48 FR 28194; June 21, 1983). The Commission explained that the purpose of the technical criteria was "to define more clearly the bases upon which licensing determinations will be made...." (48 FR 28195). The Commission acknowledged that licensing decisions would be complicated by the uncertainties that are associated with predicting the behavior of a geologic repository over thousands of years and stated that it intended to address this difficulty by requiring that a DOE proposal be based upon a multiple barrier approach:

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<sup>2</sup>Section 801(b)(2) of EnPA did place a further restriction on NRC's rules for a repository by requiring NRC to incorporate into its rules assumptions, consistent with the findings and recommendations of the National Academy of Sciences (NAS), pertaining to the sufficiency of engineered barriers and DOE's post-closure oversight to prevent human activity causing a breach of the repository and to prevent any increase in the exposure of individual members of the public to radiation beyond allowable limits. However, NAS concluded that these assumptions were not scientifically justified and Part 63 is not based on these assumptions.

An engineered barrier system is required to compensate for uncertainties in predicting the performance of the geologic setting, especially during the period of high radioactivity. Similarly, because the performance of the engineered barrier system is also subject to considerable uncertainty, the geologic setting must be able to contribute significantly to isolation.

Id. The Commission did not specify that either the engineered or the geologic barriers be primary. However, the Commission did elect to implement this approach by establishing a number of performance objectives and detailed siting and design criteria that it “deemed appropriate” for a multi-barrier system. Id., fn 2. The Commission identified “two potentially viable approaches” to achieving the goal of waste isolation: (a) an approach “that would prescribe minimum performance standards for each of the major elements of the geologic repository, in addition to prescribing the EPA standard as a single overall performance standard;” and (b) an approach “that would specify the EPA standard as the sole measure of isolation performance” (48 FR 28196). In short, the Commission believed it was legally free to adopt either approach. The Commission adopted the first approach in order to convey “in [a] meaningful way the degree of confidence which it expects must be achieved in order for it to be able to make the required licensing decisions.” Id. It, therefore, adopted a regulation setting sub-system performance standards, although with a provision allowing modifications on a case-by-case basis.<sup>3</sup> See 10 CFR 60.113.

As explained above, EnPA required NRC to modify its technical requirements to assure consistency with EPA’s standards for a repository at YM. In response to this mandate, NRC published a proposed rule to establish a new, separate part of its regulations at 10 CFR Part 63.

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<sup>3</sup>Contrary to petitioner’s assertions, the Commission did not view the sub-system requirements as the “essential prerequisites to establishing a safe repository,” Petition at 22, but rather as a means of increasing confidence in its licensing decisions, given the uncertainties and technical methods for evaluating repository performance available in 1983.

(64 FR 8640; February 22, 1999). The proposed rule was designed to do more than simply conform NRC's technical requirements to an EPA standard. The Commission recognized that in the 15 years since the Part 60 technical criteria had been put in place, there had been "considerable evolution in the capability of technical methods for assessing the performance of a geologic repository at Yucca Mountain [and that] .... their implementation for Yucca Mountain [would] avoid the imposition of unnecessary, ambiguous, or potentially conflicting criteria that could result from the application of some of the Commission's generic requirements at 10 CFR Part 60" (64 FR 8641). In addition, the Commission recognized an opportunity to establish criteria compatible with the Commission's overall philosophy of risk-informed, performance-based regulation:

[T]he creation of a new part of its regulations to [achieve risk-informed, performance-based regulations] is preferable to modifying its generic requirements, given the fundamentally different approach laid out for Yucca Mountain by EnPA and NAS than was contemplated when the generic criteria were promulgated. More specifically, EnPA and NAS have specified an approach that would require the performance of a Yucca Mountain repository to comply with a health-based standard established in consideration of risk to a hypothetical critical group, and, further, that this would be the only quantitative standard for the post-closure performance of the repository. This approach is incompatible with the approach taken in the existing generic criteria which relies on quantitative, subsystem performance standards.

(64 FR 8643). The Commission decided to reexamine its implementation of a multiple barrier approach and propose a regulation which required a system of multiple barriers but which did not assess the performance of those barriers by establishing numerical goals for the performance of individual barriers. See 64 FR 8647 - 8650. Instead, DOE was required to demonstrate that the

natural barriers and the engineered barrier system would work in combination to enhance overall performance of the geologic repository.<sup>4</sup>

In the final rule (66 FR 55732; November 2, 2001), the Commission clarified the intent of NWPA's multi-barrier provision:

Section 63.113(a) requires that the geologic repository include multiple barriers, both natural and engineered. Geologic disposal of HLW is predicated on the expectation that one or more aspects of the geologic setting will be capable of contributing to the isolation of radioactive waste and thus be a barrier important to waste isolation.... The performance assessment provides an evaluation of the repository performance based on credible methods and parameters including the consideration of uncertainty in the behavior of the repository system. Thus the performance assessment results reflect the capability of each of the barriers to cope with a variety of challenges.... A description of each barrier's capability ... as reflected in the performance assessment, provides an understanding of how the natural barriers and the engineered barrier system work in combination to enhance the resiliency of the geologic repository. The Commission believes that this understanding can increase confidence that the postclosure performance objectives specified at § 63.113(b) and (c) will be achieved and that DOE's design includes a system of multiple barriers.

10 CFR 63.102(h); see 66 FR 55758. The Commission placed the requirements for multiple barriers in § 63.115.

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<sup>4</sup>In this reexamination, the Commission noted that the § 60.113 subsystem criteria "[had] not gained broad acceptance in the technical community" and had been "criticized as overly prescriptive, lacking in both a strong technical basis and a clear technical nexus to the overall performance objective...." (64 FR 8649). Further, the Commission noted that NAS had found, in 1995, that "the physical and geologic processes relevant to a Yucca Mountain repository... are sufficiently quantifiable and the related uncertainties sufficiently boundable that the performance of a repository can be assessed over timeframes during which the geological system is relatively stable or varies in a boundable manner." (64 FR 8649 (quotations omitted)). Moreover, "experience and improvements in the technology of performance assessment, acquired over more than 15 years, now provide significantly greater confidence in the technical ability to assess comprehensively overall repository performance, and to address and quantify the corresponding uncertainty." (64 FR 8649).



In sum, the NWPA as enacted in 1982 requires that NRC's regulations for a repository must specify the use of a system of multiple barriers. Neither Congress' amendment of NWPA in 1987 nor its enactment of EnPA in 1992 altered that direction. None of this legislation required that geologic considerations were to be the primary criteria for licensing a repository. NRC's technical criteria in Part 60, issued in 1983 in response to NWPA's direction, did not make geologic barriers the primary criteria but did, in implementing the multi-barrier requirement, set separate numerical criteria for both the engineered and the geologic barriers to meet. NRC reconsidered this approach in 2001 when it issued regulations governing DOE's license application for a repository at YM and decided not to include subsystem requirements. NRC provided a detailed explanation of its reasons for altering its approach for implementing NWPA's multi-barrier requirement. We have no doubt that Part 63 fully complies with Congress' statutory directions to NRC.

Petitioner ignores section 121 of NWPA - which speaks directly to NRC's duty with respect to issuing regulations for the repository - and, instead, locates the asserted duty of the Commission to establish regulations requiring that geologic isolation be the primary form of containment for HLW in sections 112(a) and 113(b)(1) of the NWPA, 42 U.S.C. sec. 10132(a) and 10133(b)(1).<sup>5</sup> Petition at 11-18. Because these provisions of NWPA place obligations on DOE, rather than NRC, they do not govern NRC's rulemakings for a geologic repository.

As relevant here, section 112(a) provides:

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<sup>5</sup>The 1987 amendments to NWPA did not revise section 112(a) but did revise section 113(b) to make its provisions applicable solely to the characterization of the YM site, rather than any candidate site.

SEC. 112.(a) GUIDELINES. –Not later than 180 days after the date of enactment of this Act, the Secretary, following consultation with the Council on Environmental Quality, the Administrator of the Environmental Protection Agency, the Director of the Geological Survey, and interested Governors, and the concurrence of the Commission shall issue general guidelines for the recommendation of sites for repositories. Such guidelines shall specify detailed geologic considerations that shall be primary criteria for the selection of sites in various geologic media. Such guidelines shall specify factors that qualify or disqualify any site from development as a repository .... Such guidelines shall require the Secretary to consider the various geologic media in which sites for repositories may be located and, to the extent practicable, to recommend sites in different geologic media. The Secretary shall use guidelines established under this subsection in considering candidate sites for recommendation under subsection (b). The Secretary may revise such guidelines from time to time, consistent with the provisions of this subsection.

42 U.S.C. sec. 10132(a). Under section 112(b), the Secretary is to nominate at least 5 sites determined to be suitable for site characterization and, subsequent to such nomination, to recommend to the President 3 of the nominated sites for characterization as candidate sites. Each nomination of a site is to be accompanied by an environmental assessment which includes, inter alia, “an evaluation by the Secretary as to whether such site is suitable for site characterization under the guidelines established under subsection (a).” Section 112(b)(1)(D)(i).

The most obvious reason why these provisions of NWPA do not mandate that NRC issue regulations requiring that geologic barriers be primary is that these provisions give direction to the Secretary of DOE, not to NRC. Petitioner assumes that the mandate given to DOE to formulate guidelines for the nomination, and then selection, of sites for characterization applies equally to NRC in promulgating its regulations. But there is no statutory language to support this. Petitioner may believe that although the statute itself is silent on any NRC duty to make geologic barriers primary, this result must necessarily follow from the duty placed on DOE to issue guidelines specifying “detailed geologic considerations that shall be primary criteria for the selection of sites in various geologic media.” Section 112(a). It may be readily acknowledged that it would make

little sense for Congress to establish a system for selecting a repository where DOE guidelines for selection of sites and NRC regulations for licensing a repository would contradict each other.<sup>6</sup> But there is no such contradiction. DOE's guidelines are for the purpose of comparing a multitude of alternate site possibilities, an inquiry where it makes obvious good sense for geologic considerations to be paramount.<sup>7</sup> NRC's licensing regulations are for the purpose of examining DOE's application for a repository at an already-chosen site -- i.e., one that has gone through the section 112 screening process. Such a site would have already passed the section 112 tests for geologic considerations in the DOE guidelines. Congress had no need to require, and did not require, NRC to issue regulations making geologic considerations the "primary" criteria for approval of DOE's license application for the repository.

Petitioner seeks to bootstrap the section 112(a) site selection guidelines into the requirement in section 113 that DOE prepare a site characterization plan, for site characterization activities at YM, which shall include "criteria to be used to determine the suitability of such candidate site for the location of a repository, developed pursuant to section 112(a)." Section 113(b)(1)(A)(iv). Petition at 11-12. If the criteria for site characterization for determination of suitability for a repository required by section 113 are the same as the guidelines required by section 112, then, petitioner assumes, DOE may not recommend a site to the President for approval under section 114 unless the site has been shown to meet the guidelines, including the

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<sup>6</sup>In fact, DOE's need to seek NRC's concurrence on its guidelines assures that there will be no such conflict.

<sup>7</sup>As enacted in 1982, the section 112(a) guidelines were intended for use in the nomination and selection of candidate sites for a second repository as well as for the identification and study of further sites after the approval of candidate sites for characterization for two repositories. See sections 112(b)(1)(C) and 112(d) of the 1982 NWPAA.

guideline that geologic considerations be the primary criteria for selection, and NRC must promulgate regulations requiring that geologic considerations be the primary criteria for approval of a license application.

Petitioner makes several unwarranted leaps in arriving at these conclusions. The first is that Congress intended that the criteria required under section 113 be the same as the guidelines required under section 112. DOE considered this question at considerable length when it issued its criteria for consideration of the YM site. (66 FR 57298, 57311 - 57312; November 14, 2001). DOE concluded that Congress' directive in section 113(b)(1)(A)(iv) that the criteria to be used to determine the suitability of a candidate site for the location of a repository be "developed pursuant to section 112(a)" is best understood as "mandating observance of the special procedural requirements of section 112(a) in formulating or altering the section 113(b) 'criteria,'" i.e, the requirements to consult with specific agencies and to get concurrence from NRC, and not as requiring that the "criteria" be the guidelines themselves. (66 FR 57312). Second, even assuming, arguendo, that the criteria were intended to be the guidelines - and we have no reason to quarrel with DOE's interpretation of its own statutory mandate - that still would not oblige NRC to craft its regulations under DOE's criteria. There would be no contradiction between DOE's recommending a site as suitable for a repository, based primarily on geologic considerations, and NRC's issuing regulations under which a repository would be approved, based upon the existence of multiple barriers, but not necessarily on geologic "primacy."

In sum, because sections 112 and 113 of NWSA place no obligations on NRC with respect to rulemakings for a geologic repository, and because Part 63 is in full conformance with section

121 of NWPA which does spell out NRC's rulemaking obligations, we reject petitioner's claim that Part 63 is not in full conformance with NWPA and deny the petition.

b. 10 CFR Part 63 is in accord with AEA requirements.

Petitioner asserts that because Part 63 does not demand that the applicant provide "an affirmative safety case" for the repository, "the rule is materially deficient." Petition at 4. In petitioner's view, a requirement that DOE conduct a total system performance assessment "to determine whether a primary radiological standard set by the EPA can be met by the overall repository system, and not by any particular subsystem or any particular isolation barrier" is not adequate. Petition at 22. Rather, "under NRC's plenary safety jurisdiction (Atomic Energy Act Section 161b) ... it would remain NRC's legal obligation to apply these basic scientific prerequisites [found in section 112(a) of NWPA] in providing for reasonable assurance of the safety of the repository ...."<sup>8</sup> Id.; see also petition at 32.

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<sup>8</sup>Petitioner erroneously believes that DOE was exempt from regulation by NRC under section 161b. of the AEA until passage of NWPA in 1982. In fact, NRC's authority over DOE, with respect to an application for a license for a geologic repository, stems from section 202(3) of the Energy Reorganization Act of 1974 (ERA), 42 U.S.C. sec. 5842(3), which provides that NRC shall ... have licensing and related regulatory authority pursuant to chapters 6, 7, 8, and 10 of the [AEA] [with respect to DOE] "facilities used primarily for the receipt and storage of [HLW] resulting from activities licensed under [the AEA]." Thus, in 1981, when NRC issued its original rule governing a DOE license application for a repository at 10 CFR Part 60, the Commission cited section 202 as the authority for the rule, noting that it interpreted "storage" as used in this section to include disposal. (46 FR 13971; February 25, 1981), n.1. Neither NWPA nor EnPA provided NRC with rulemaking authority; rather NWPA directed NRC, "pursuant to authority under other provisions of law," to promulgate the technical requirements and criteria it would employ to consider a DOE license application for a repository (sec. 121(b) of NWPA) and EnPA required NRC to modify its technical requirements to be consistent with standards to be promulgated by EPA. Section 801(b)(1) of EnPA. For these reasons, we agree with petitioner that Part 63 must be consistent with section 161b. of the AEA.

Section 161b. of the AEA provides, in relevant part:

Sec. 161. General Provisions.

In the performance of its functions the Commission is authorized to --

...

(b). establish by rule, regulation, or order, such standards and instructions to govern the possession and use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life and property ...

We agree with petitioner that “[t]his is clearly an extremely broad grant of authority.”

Petition at 6, n.2. The Commission is granted wide discretion to determine what standards are necessary or desirable to protect health and minimize danger to life and property. Through an extensive and open public process, the Commission set forth its post-closure public health and environmental standards in Subpart L of Part 63. Petitioner, however, is dissatisfied with these standards and would require inclusion of the DOE guidelines listed in section 112(a) of NWPA and/or the requirements preferred by the Peer Review. However, there is no statute requiring the Commission to make these choices rather than the standards the Commission, in fact, deemed sufficient for a determination that the repository will not pose an unreasonable risk to the health and safety of the public. See 10 CFR 63.31(a)(2); 63.41(c). Petitioner has not presented any new information that causes the Commission to reconsider choices already made in an extensive and recent rulemaking proceeding. See infra. Thus, we remain satisfied that the Part 63 rules fully comply with the Commission’s duty, under section 161b. of the AEA to establish standards to protect health and minimize danger to life and property.

2. Reopening the final 10 CFR Part 63 rule would be an unwise expenditure of resources because the Petition does not appear to present any significant new factual information not previously considered during the rulemaking proceeding.

On February 22, 1999 (64 FR 8640), the Commission published its proposed rule to establish licensing criteria for the disposal of HLW in the proposed geologic repository at YM. The public comment period, originally ending on May 10, 1999, was extended to June 30, 1999, in response to many requests for extension. During the public comment period, the NRC staff held a series of public meetings in Nevada to discuss the proposed rule and solicit public comment. The final rule was published on November 2, 2001 (66 FR 55732). Petitioner had multiple opportunities to file, and did file, extensive comments on the proposed rule, all of which were carefully considered by the Commission before issuing the final rule. We do not find in the petition significant new factual or policy information not already considered in the rulemaking that established Part 63. Given this, and our very recent consideration (in the Part 63 rulemaking) of essentially the same questions petitioner now raises, it would not be a wise expenditure of resources to reopen these issues. We briefly recount below the concerns that petitioner now raises as “material deficiencies,” but were in actuality resolved in the Part 63 rulemaking.

#### Reasonable Expectation

Petitioner objects to the Commission’s use of “reasonable expectation,” rather than “reasonable assurance,” to describe the degree of certainty to be obtained for the compliance of the repository with the post-closure performance standards. Petition at 3, n.1. The Commission has fully explained why it incorporated “reasonable expectation,” rather than “reasonable

assurance,” into its implementing regulations for YM. See 66 FR 55739 - 55740; November 2, 2001. The Commission stated that “irrespective of the term used, the Commission will consider the full record before it [and] [t]hat record will include many factors in addition to whether the site and design comply with the performance objectives (both preclosure and postclosure performance standards) contained in Subparts E, K and L” (66 FR 55740).<sup>9</sup> Petitioner has not raised any objection to this standard that was not already fully considered. Thus, we decline to amend Part 63 to reverse the decision made in the rulemaking for Part 63.

#### Primacy of the Geologic Barrier

Petitioner requests that Part 63 be revised to require that the geologic setting of the YM site be the primary barrier against release of radionuclides to the biosphere and a separate criterion be specified for the geologic setting; i.e., pre-waste-emplacement groundwater travel time along the fastest path of likely radionuclide travel from the disturbed zone to the accessible environment of at least 1,000 years. The role of the geologic setting, including the imposition of separate criteria for individual barriers (or sub-system requirements) was an important consideration during the development of Part 63. NRC’s generic regulations for HLW disposal at 10 CFR Part 60 prescribe criteria for individual barriers. Petitioner’s request would serve to continue the Part 60 sub-system approach. See § 60. 113(a)(2).

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<sup>9</sup>The Commission noted that it “could consider the QA program, personnel training program, emergency plan and operating procedures, among others, in order to determine whether it has confidence that there is no unreasonable risk to the health and safety of the public” (66 FR 55740; November 2, 2001).



The Commission carefully considered the merits of including these types of barrier criteria when it proposed Part 63, but decided against doing so:

Upon review ... the Commission is persuaded that much of the basis for NRC's initial development of the specific numerical values for the subsystem criteria was generic judgment with regard to what was (and was not) feasible with regard to the quantitative assessment of long-term repository performance. Because the stated goal was to compensate for uncertainty, there was never any attempt to derive the subsystem performance criteria from a specified dose or risk level or from some projected dose or risk reduction expected to be achieved by their application. Furthermore, after 15 years of experience in working with the requirements of Part 60, the Commission is concerned that, for the Yucca Mountain site, the application of the subsystem performance criteria at § 60.113 may impose significant additional expenditure of resources on the nation's HLW program, without producing any commensurate increase in the protection of public health and safety.

(64 FR 8649; February 22, 1999). Nevertheless, the Commission acknowledged the importance of the geologic setting:

[D]espite its reconsideration of the merits of establishing quantitative criteria for the performance of repository subsystems, the Commission continues to believe that multiple barriers, as required by NWPA, must each make a definite contribution to the isolation of waste at Yucca Mountain, so that the Commission may find, with reasonable assurance, that the repository system will be able to achieve the overall safety objective over timeframes of thousands of years. Geologic disposal of HLW is predicated on the expectation that a portion of the geologic setting will act as a barrier, both to water reaching the waste, and to dissolved radionuclides migrating away from the repository, and thus, contribute to the isolation of radioactive waste.

Id. The proposed rule required DOE to provide an analysis that (1) identifies those design features of the engineered barrier system, and natural features of the geologic setting, that are considered barriers important to waste isolation; (2) describes the capability of these barriers to isolate waste, taking into account uncertainties in characterizing and modeling the barriers; and (3) provides the technical basis for the description of the capability of these barriers. The

Commission stated that this approach would “provide for a system of multiple barriers and an understanding of the resiliency of the geologic repository provided by the barriers important to waste isolation to ensure defense in depth and increase confidence that the postclosure performance objective will be achieved.”

(64 FR 8650; February 22, 1999).

NRC received comments both supporting and opposing its proposed approach for evaluating individual barriers, including a comment from petitioner requesting that the Part 60 approach be retained. After careful consideration of these comments, the Commission decided to retain the proposed approach because:

1. It provides the Commission with information to be considered in its decisions without constraining its considerations to a specific limit for a particular barrier, which could result in less favorable overall system performance.
2. It gives the Commission the flexibility to consider the nature and extent of conservatism in the evaluations used for compliance demonstration, and to decide whether there is a need to require DOE to reduce uncertainties in its assessment (e.g., collecting more site data) or to include further mitigative measures.
3. Quantitative evidence of the capability of individual barriers to contribute to waste isolation is an integral part of the performance assessment. Therefore, an additional quantitative limit is not necessary to show that overall performance reflects a system of multiple barriers.

The Commission understands that establishment of explicit, quantitative limits for individual barriers might be considered a desirable and more easily explained approach. That being said, however, the Commission knows of no scientific basis for setting such limits for particular barriers at Yucca Mountain, or at any other site, independent of the complex repository system in which they must perform. The Commission is confident that evidence for the resilience, or lack of resilience, of a multiple-barrier system will be found by examining a comprehensive and properly documented performance assessment of the behavior of the overall repository system. Such an assessment must consider credible and supportable ranges of individual parameters and modeling assumptions, and must include multiple evaluations of a wide range of combinations of resulting barrier performance.

(66 FR 55759; November 2, 2001).

In sum, the Commission devoted considerable attention in its rulemaking proceeding to the question whether it should retain the subsystem requirements of Part 60 which would establish quantitative performance criteria for the geologic barriers but decided against this approach. Petitioner is dissatisfied with this outcome and essentially seeks reconsideration of this decision. However, petitioner has presented no significant new information to support this request and it would be an unwise expenditure of resources to cover this same ground again in a new rulemaking.<sup>10</sup>

#### Potentially Disqualifying Conditions

NRC's generic Part 60 regulations contain siting criteria which include "potentially adverse conditions" which must be shown not to compromise the ability of the repository to meet the performance objectives for isolation of the wastes. See § 60.122. Petitioner seeks to amend Part 63 to include many of these potentially adverse conditions as "potentially disqualifying conditions" and to require the applicant to show that they do not exist or, if they do exist, "that they are not materially adverse to the long-term safety of the repository." Petition at 41 - 43.

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<sup>10</sup>Petitioner cites a 1999 DOE analysis of the independent capabilities of the multiple waste isolation barriers which indicated that the engineered barriers contribute over 99.7 percent of the waste isolation capabilities of the repository system, implying that NRC will not really apply a "multiple barrier" approach because the geologic contributions of YM are minuscule. Petition at 27, n.16. But our rules on their face unequivocally require "multiple barriers," as called for by NWPA. See discussion, supra. Our consideration of the nature of DOE's proposed facility must await a DOE license application.

In proposing Part 63, the Commission specified overall performance objectives for the preclosure and postclosure phases of the repository and requirements that compliance with these overall performance objectives be demonstrated through an integrated safety analysis of preclosure operations, and through a performance assessment for long-term, post-closure performance. The proposal did not specify potentially adverse conditions to be considered but did require that the performance assessment consider unfavorable, as well as favorable, information:

A defensible performance assessment should contain a technical rationale for those features, events, and processes that have been included in the performance calculation, as well as those that have been considered but were excluded. The features, events, and processes (i.e., specific conditions or attributes of the geologic setting; degradation, deterioration, or alteration of the engineered barriers; and interactions between the natural and engineered barriers) conducted for inclusion in the assessment should represent a wide range of beneficial and detrimental effects on performance.

(64 FR 8650; February 22, 1999). Public comments on the proposed rule raised concerns about the impacts of certain features, events, and processes (e.g., that YM lies in an area that is seismically and tectonically active; that there may be potential for fast ground-water pathways to the water table) that prompted many commenters to recommend that YM be disqualified from further consideration. The Commission considered these objections but reaffirmed the approach it had decided to take in the proposed rule:

Consideration of all FEPs, especially those with the potential to have an adverse effect on performance, is an important part of the evaluation of repository performance. Commenters have correctly identified a number of conditions that have been or are being considered by DOE in performance assessments for Yucca Mountain, such as seismic activity, thermal effects, volcanic activity, microbial-induced corrosion of the waste package, and the potential for a significant rise of the water table. Section 63.114 requires DOE to consider all FEPs pertinent to a repository at Yucca Mountain and fully justify how they are treated in the performance assessment. In reviewing DOE's performance assessment, the NRC will evaluate how well DOE has accounted for those FEPs that could have an adverse effect on the repository.

(66 FR 55748; November 2, 2001). Thus, the Commission considered in the Part 63 rulemaking whether it should specify disqualifying conditions for the repository site but decided that its approach of having the performance assessment present and consider all information relevant to negative conditions was preferable. The Commission finds no reason presented by petitioner to reopen that issue.

#### Peak Radiation Doses Subsequent to the Regulatory Monitoring Period

Petitioner requests that § 63.113 be amended to add the following provision:

Peak Dose. The geologic setting for the Yucca Mountain repository shall evidence sufficient geologic suitability to provide reasonable assurance that peak radiation doses to the accessible environment will not occur subsequent to the regulatory monitoring period established by the Environmental Protection Agency in 40 C.F.R. Part 197.

Petition at 43. This requirement is needed because, in petitioner's view, "the repository will become most dangerous to humans and the environment *after* the EPA's prescribed regulatory time period." Petition at 33 (emphasis in original). Petitioner supports this view with a graphic produced in the July 2002 National Geographic using data provided in DOE's Final Environmental Impact Statement, DOE/EIS-0250 (February 2002). Petition, Attachment 2. According to petitioner, this graphic illustrates that "DOE's own models predict that radiation doses from Yucca Mountain releases to the accessible environment will not begin to peak until after the 10,000-year regulatory time period that forms the basis for Part 63 licensing." Petition at 33.

Petitioner believes that NRC must have reasonable assurance that the peak radiation doses to the accessible environment will occur within the regulatory compliance period.<sup>11</sup> This amounts to a challenge to the 10,000 year compliance period adopted by the Commission in Part 63. The Commission proposed a 10,000 year compliance period for evaluating a YM repository because it:

(1) includes the period when the waste is inherently most hazardous; (2) is sufficiently long, such that a wide range of conditions will occur which will challenge the natural and the engineered barriers, providing a reasonable evaluation of the robustness of the geologic repository; and (3) is consistent with other regulations involving geologic disposal of long-lived hazardous materials, including radionuclides.

(64 FR 8647; February 22, 1999). The Commission acknowledged that, on this matter, it was not following the recommendation made by NAS that the compliance period should include the time when greatest risk occurs, within the limits imposed by the stability of the geologic system.

However, the Commission explained:

In selecting the length of time over which the individual dose limit should be applied, a regulatory agency must take into account technical, policy, and legal considerations. In fact, NAS noted that EPA might elect to establish consistent policies for managing comparable risks from disposal of long-lived hazardous materials. From a technical perspective, for example, the time-dependent variation of the hazard, along with the time required to evaluate adequately the waste isolation capability of both engineered and natural barriers, are of significance. From a policy perspective, on the other hand, the practical utility and relative uncertainty of extremely long projections of health consequences, along with the need to maintain a consistent regulatory approach for like hazards, need to be weighed. Having considered both technical and policy concerns, the Commission is proposing the use of 10,000 years for evaluating compliance with the system performance objective at § 63.113.

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<sup>11</sup>We interpret petitioner's reference to "the regulatory monitoring period established by the Environmental Protection Agency in 40 C.F.R. 197" to be a reference to the 10,000 year compliance period established in EPA's regulations since those regulations do not include a monitoring period.

Id. The Commission received comments objecting to this proposal but decided to reaffirm use of a 10,000 year compliance period in the final rule:

The fact that it is feasible to calculate performance of the engineered and geologic barriers making up the repository system for periods much longer than 10,000 years does not mean that it is possible to make realistic or meaningful projections of human exposure and risk, attributable to releases from the repository, over comparable time frames. NAS acknowledged that projecting the behavior of human society over long periods is beyond the limits of scientific analysis and recommended that 'cautious, but reasonable' assumptions, based upon current knowledge, be made with regard to the selection of biosphere and critical group parameters for Yucca Mountain. Determining just how far into the future current knowledge can no longer support 'reasonable' assumptions about pathways affecting human exposure is clearly a subjective, policy judgment. NRC believes that, for periods approaching 1,000,000 years, as suggested by NAS, during which significant climatic and even human evolution would almost certainly occur, it is all but impossible to make useful and informed assumptions about human behaviors and exposure pathways.

(66 FR 55760; November 2, 2001).

Thus, the Commission has considered the appropriate length of the compliance period and has determined that 10,000 years is an acceptable period for assessing compliance with performance standards. The Commission also adopted an EPA standard requiring DOE to calculate the peak dose of the reasonably maximally exposed individual that would occur after 10,000 years following disposal but did not apply a regulatory standard to the results of this analysis. Instead, DOE is to include the results of the analyses and their bases in the environmental impact statement for YM as an indicator of long-term disposal system performance. See § 63.341; see also 40 CFR 197.35. The Commission continues to believe, as articulated in the both the proposed and final regulations, that potential radiation exposures estimated at very

long times into the future (e.g., 100,000 years and longer), as shown in the National Geographic graphic, are too speculative to provide meaningful information to make licensing decisions.

#### Need for Presentation of an Affirmative Safety Case

Petitioner believes that DOE must be required to present “an affirmative safety case” which demonstrates an understanding of repository performance. To ensure demonstration of an affirmative safety case, petitioner has proposed a new regulation (proposed § 63.21(c), supra) which is based on, but not identical to, recommendations made by the Peer Review with respect to DOE’s TSPA-SR.<sup>12</sup> Although the Peer Review focused on DOE’s TSPA-SR, it did make a few observations on NRC’s proposed Part 63:

The regulations require that a risk-informed approach should be adopted in demonstrating compliance with the dose limit, in recognition of the uncertainties inherent in making assessments over long time frames in the future. It is also required that the assessment should reveal an understanding of the relationship between the performance of the repository sub-systems and the total system performance. Nevertheless despite the prescriptive nature of the regulations, the I[n]ternational R[eview] T[eam] notes that the proposed licensing regulation 10 CFR 63 states that “*consistent with a performance based philosophy, the Commission proposes to permit DOE the flexibility to select the approach for demonstrating this relationship that is most appropriate to its analysis.*”

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<sup>12</sup>The Peer Review expressed the view that the TSPA-SR could be improved with respect to developing a better understanding of the repository system:

The TSPA-SR methodology embodies a comprehensive computational framework for estimating possible doses to future generations using a complex systems-level model accounting for hundreds of features, events and processes and related parameter ranges. A key issue with this approach is the difficulty in understanding the meaning of the numerical results. In particular, it is often difficult to understand how the system is likely to evolve and which process and parameters are the most important.

Peer Review at 41.



In its review of the TSPA-SR, the IRT has observed a tendency for more focus to be given to the demonstration of numerical compliance with the proposed regulatory requirements than on developing and presenting an understanding of repository performance. Whilst it is completely understandable that the TSPA-SR should give due attention to demonstrating compliance with the prescribed dose limit, an in-depth understanding of the performance of the repository system is necessary to develop confidence in the overall design and safety of the repository and in the results of the assessment. In this regard, there is an emerging international consensus that building confidence in repository performance is of comparable importance to demonstrating compliance with criteria. Thus it is recommended that in the future equal attention should be given to system understanding as to numerical compliance with regulatory criteria if the project proceeds to the licensing stage.

Peer Review at 23-24 (emphasis in original).

Thus, the Peer Review acknowledged the importance of DOE presenting, in its TSPA, an in-depth understanding of the performance of the repository system and recognized that demonstration of safety is more than numerical compliance with the proposed regulatory requirements. As a matter of record, a similar concern was raised during the public comment period on the proposed regulation (i.e., can performance assessment be relied on as the sole quantitative technique for evaluating compliance with the postclosure safety requirements). The Commission, in response to this concern, explained that the regulations contained a number of requirements directed at DOE's demonstrating an in-depth understanding of the repository system:

Although repository postclosure performance is evaluated with respect to a single performance measure for individual protection, the NRC considers a broad range of information in arriving at a licensing decision. In the case of the proposed repository at Yucca Mountain, Part 63 contains a number of requirements (e.g., qualitative requirements for data and other information, the consideration and treatment of uncertainties, the demonstration of multiple barriers, performance confirmation program, and QA program) designed to increase confidence that the postclosure performance objective is satisfied. The Commission will rely on the performance assessment as well as DOE's compliance with these other requirements in making a decision, if DOE submits a license application for disposal of HLW at Yucca Mountain.

(66 FR 55746; November 2, 2001).

The current regulations require that DOE provide an adequate and appropriate understanding of the repository system as part of its compliance demonstration. For example, the requirements for the performance assessment, at § 63.114, specify that DOE must account for uncertainty in representing the repository system (both in parameters and models); provide a technical basis for either inclusion or exclusion of specific features, events, and processes in the performance assessment including the degradation, deterioration, or alteration processes of engineered and geologic barriers; and provide a technical basis for the models used in the performance assessment such as comparisons made with outputs of detailed process-level models and/or empirical observations (e.g., laboratory testing, field investigations, and natural analogs). Additionally, the requirements for multiple barriers, at § 63.115, specify that DOE must identify those design features of the engineered barrier system, and natural features of the geologic setting, that are considered barriers important to waste isolation; describe the capability of barriers identified as important to waste isolation actually to isolate waste, taking into account uncertainties in characterizing and modeling the behavior of the barriers; and provide the technical basis for the description of the capability of barriers.

In summary, the current regulations require that DOE demonstrate an adequate and appropriate understanding of the repository system, supported by technical and scientific information that includes a range of important technical concerns such as the features, events, and processes that could affect the performance of the repository; evaluation of how uncertainty in

parameters and models affects the estimates of repository performance; and the capabilities of the engineered and geologic barriers to isolate waste.

Petitioner had full opportunity during the extensive Part 63 rulemaking to suggest additional requirements for DOE's application to provide greater understanding of the repository system, and did so in its comments questioning the appropriateness of the Commission's proposal to establish risk-informed, performance based regulations which would not include the existing sub-system performance requirements of Part 60. The Peer Review, although published after NRC's issuance of the final rule, is based on information widely available during NRC's rulemaking proceeding (e.g.; U.S. NRC Advisory Committee on Nuclear Waste Letter to Chairman Jackson, dated April 8, 1999, "SR 95 Template for Safety Reports with Descriptive Example," Swedish Nuclear Power Inspectorate, Technical Report 96-05). Thus, the Peer Review did not present new information with respect to Part 63; it presented a critique of DOE's TSPA-SR. Consequently, we do not believe that the Peer Review, or other critiques of DOE's activities at YM, justifies expending the resources that would be needed to reopen the issues considered in the recent Part 63 rulemaking.

For all the reasons stated above, the NRC denies the petition in its entirety.

Dated at Rockville, Maryland, this \_\_\_\_\_ day of \_\_\_\_\_, 2003.

For the Nuclear Regulatory Commission,

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Annette Vietti-Cook

Secretary of the Commission